

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

June 6, 2006

Date of Report (Date of earliest event reported)

Discovery Laboratories, Inc.

(Exact name of Company as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

000-26422

(Commission File Number)

94-3171943

(IRS Employer
Identification Number)

2600 Kelly Road, Suite 100

Warrington, Pennsylvania 18976-3622

(Address of principal executive offices)

(215) 488-9300

(Company's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the Company under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 8.01. Other Events.

On June 6, 2006, Discovery Laboratories, Inc. (the “Company”) issued a press release to announce that it has notified the European Medicines Evaluation Agency of its decision to voluntarily withdraw the Marketing Authorization Application for Surfaxin[®] for the prevention and treatment of Respiratory Distress Syndrome in premature infants. The full text of the press release is set forth in Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

99.1 Press Release dated June 6, 2006.

Cautionary Note Regarding Forward-looking Statements:

To the extent that statements in this Current Report on Form 8-K are not strictly historical, including statements as to business strategy, outlook, objectives, future milestones, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of the Company’s product development or otherwise as to future events, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements contained in this Current Report are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Such risks and others are further described in the Company’s filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Discovery Laboratories, Inc.

By: /s/ Robert J. Capetola

Robert J. Capetola, Ph.D.
President and Chief Executive Officer

Date: June 7, 2006



Discovery Labs Withdraws European Marketing Application for Surfaxin®

Warrington, PA — June 6, 2006 — Discovery Laboratories, Inc. (Nasdaq: DSCO), today announced that it has notified the European Medicines Evaluation Agency (EMA) of its decision to voluntarily withdraw the Marketing Authorization Application (MAA) for Surfaxin® for the prevention and treatment of Respiratory Distress Syndrome (RDS) in premature infants. The decision to withdraw is based on recently announced manufacturing issues that Discovery has now determined can not be resolved within the MAA review timetable. Withdrawal precludes resolution of certain outstanding clinical issues, which were the focus of a recent EMA clinical expert meeting and relate to the Surfaxin Phase 3 clinical trials (including the design and lack of comparison to Curosurf®, the leading surfactant in Europe), that also may not have been resolvable within the current MAA review timetable. As a consequence, additional clinical trials may be required to support approval of Surfaxin for RDS in Europe through the centralized procedure.

Discovery's New Drug Application to the United States Food & Drug Administration (FDA) is supported with data from Discovery's Phase 3 SELECT and STAR trials. The FDA has issued Discovery a second Approvable Letter, which contains conditions that must be satisfied by Discovery prior to obtaining final U.S. marketing approval. Consistent with previous review, the FDA does not have any clinical or statistical comments.

Discovery previously announced that certain stability parameters from the Surfaxin process validation batches had not been achieved. As a result, additional process validation batches will have to be produced, which will take longer than the allotted MAA review timetable. The European centralized regulatory procedure does not provide a mechanism for placing an application on hold at this stage in the review process, or allow a company to add new information to the MAA. Discovery intends to have further discussions with the EMA and develop a strategy for potential Surfaxin approval in Europe.

Discovery submitted the MAA in October 2004. The MAA submission was supported, in large part, by data from Discovery's two positive Phase 3 RDS clinical trials. The SELECT study was a pivotal, landmark, adjudicated 1294 patient study that demonstrated Surfaxin's superiority to Exosurf®, a non-protein containing synthetic surfactant. Survanta®, a cow-derived surfactant and the leading surfactant used in the United States, served as a reference arm in the SELECT trial. The multinational SELECT study demonstrated that Surfaxin was significantly more effective in the prevention of RDS and also improved survival (continuing through at least one year of life) and other outcomes versus comparator surfactants. Discovery also conducted a 252 patient supportive study (STAR) that demonstrated Surfaxin's non-inferiority to Curosurf, a pig-derived surfactant and the leading surfactant used in Europe.

Surfaxin is a precision-engineered, peptide-containing, synthetic surfactant that is designed to closely mimic the function of natural human lung surfactant and represents a potential alternative to animal-derived surfactants.

About Discovery Labs

Discovery Laboratories, Inc. is a biotechnology company developing its proprietary surfactant technology as Surfactant Replacement Therapies (SRT) for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Discovery's technology produces a precision-engineered surfactant that is designed to closely mimic the essential properties of natural human lung surfactant. Discovery believes that through its technology, pulmonary surfactants have the potential, for the first time, to address respiratory diseases where there are few or no approved therapies available.

Discovery's lead product, Surfaxin[®], for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, has received two Approvable Letters from the FDA.

Discovery's proprietary SRT is also being developed in an aerosolized form under the name Aerosurf[™], for the treatment of neonatal respiratory disorders. Discovery is preparing to conduct Phase 2 pilot studies with Aerosurf[™], aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP). In addition, also for premature infants, Discovery recently concluded early a Phase 2 clinical trial of Surfaxin for the prevention and treatment of Bronchopulmonary Dysplasia (BPD), also known as Chronic Lung Disease. Discovery recently completed and announced preliminary results of a Phase 2 clinical trial to address Acute Respiratory Distress Syndrome (ARDS) in adults, and is also developing aerosol formulations of SRT to potentially address Acute Lung Injury (ALI), cystic fibrosis and other respiratory conditions.

For more information, please visit our corporate website at www.Discoverylabs.com.

To the extent that statements in this press release are not strictly historical, including statements as to business strategy, outlook, objectives, future milestones, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of Discovery's product development, events conditioned on stockholder or other approval, or otherwise as to future events, all such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Among the factors which could affect Discovery's actual results and could cause results to differ from those contained in these forward-looking statements are the risk that financial conditions may change, risks relating to the progress of Discovery's research and development, the risk that Discovery will not be able to raise additional capital or enter into additional collaboration agreements (including strategic alliances for aerosol and Surfactant Replacement Therapies), risk that Discovery will not be able to develop or otherwise provide for a successful sales and marketing organization in a timely manner, if at all risk that approval by the FDA or other health regulatory authorities of any applications filed by Discovery may be withheld, delayed and/or limited by indications or other label limitations, risks that any such regulatory authority will not approve the marketing and sale of a drug product even after acceptance of an application filed by Discovery for any such drug product, risks that Discovery's CMC will not satisfy the FDA, risk in the FDA or other regulatory agency review process generally, risks relating to the ability of Discovery or Discovery's third party contract manufacturers and development partners to manufacture or provide Discovery with adequate supplies of drug substance, drug products and expertise for completion of any of Discovery's clinical studies, risks relating to drug manufacturing by Discovery, risks relating to the integration of manufacturing operations into Discovery's existing operations, other risks relating to the lack of adequate supplies of drug substance and drug product for completion of any of Discovery's clinical studies, risks relating to the ability of the Company and its collaborators to develop and successfully commercialize products that will combine our drug products with innovative aerosolization technologies, risks relating to the significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval for any products that we may develop independently or in connection with our collaboration arrangements, and risks relating to the development of competing therapies and/or technologies by other companies. Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. Data obtained from tests are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. Those associated risks and others are further described in Discovery's filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto.

Company Contacts:

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